

**Remarks:**

Applicant thanks the Examiner for participating in the personal interview of 2 May 2006 with Jerad Seurer. The interview summary provided by the Examiner is mostly correct. However, the language proposed and agreed upon in the interview for amendment of Claim 1 was that "the radiation-blocking material comprises at least one of lead and tungsten".

Paragraphs 1-3 of the Office Action convey the Examiner's concerns regarding the "molded about an entirety" language of Claim 22 as supported by the specification. In the interview of 2 May 2006, Applicant pointed out that the specification clearly supports molding language (see paragraphs 15, 34, 35 and 41 of the application-as-filed). However, and as was agreed upon in the interview of 2 May 2006, Applicant has changed that language of Claim 22 to state that the polymer shell of the base completely encloses the base shielding element of the base, and that the polymer shell of the cap completely encloses the cap shielding element of the cap. Since the "molded about an entirety" language is supported by the specification, that language can now be found in new Claim 64, which depends from independent Claim 22. Accordingly, the objection to the specification and language of Claim 22 is believed to be rendered moot.

Claim 1 and a number of claims depending therefrom stand rejected under 35 USC 103 as being unpatentable over Yanke et al (Pub. No. US 2003/0141210) in view of Kronberg (US Patent No. 5,334,847). As was pointed out in the interview, Yanke et al's non-provisional patent application is not prior art over the subject matter of the pending claims; this is because Applicant's earlier filed provisional patent application (from which the present application claims priority) clearly conveys the subject matter of the invention of Claim 1 and all claims depending therefrom.

As was agreed upon in the interview of 2 May 2006, Claim 1 as currently presented is patentable over the references of record. In particular, the references of record fail to teach or suggest a radiopharmaceutical pig having:

- a base comprising a base shielding element made of a radiation-blocking material comprising at least one of lead and tungsten, a base shell that completely encloses the base shielding element and that is made of a polymer material, and a first hollow center section defined in the base; and

- a cap removably attached to the base, wherein the cap comprises a cap shielding element made of a radiation-blocking material comprising at least one of lead and tungsten, a cap shell that completely encloses the cap shielding element and that is made of a polymer material, and a second hollow center section defined in the cap.

As was discussed in the interview, Yanke et al teach away from completely enclosing a radiation shielding element inside a polymer shell. Particularly, Yanke et al (in paragraph 23) teach that the radiation shielding liner (22, 34) of their container (10) must include ribs (42, 50) to "grip" the outer casing (18, 30) of the container (10). It appears that adhesive may also be used to assist the ribs in attaching the radiation-shielding liner to the outer casing. However, there is no teaching or suggestion to remove the ribs from the liner. Accordingly, there can be no motivation for not utilizing those ribs as a means for attaching the liner to the outer casing. As

such, Yanke et al actually teaches away from completely enclosing a radiation shielding element inside a polymer shell.

As was also discussed in the interview, there is no motivation to combine Kronberg with Yanke et al. Even if such a combination was made, one would still not get to the invention of Claim 1. Kronberg discloses a radiation shielded container for storage and disposal of spent nuclear fuels and nuclear waste. This is a completely different field than that of radiopharmaceutical pigs for transporting radiopharmaceuticals. For instance, there is not a single mention of a "syringe" or a "radiopharmaceutical" in Kronberg. Accordingly, there would be no motivation to combine the references as suggested by the Examiner.

Even if one were to combine Yanke et al with Kronberg, one would still not reach the invention of Claim 1. In particular, Kronberg's container requires the inclusion of a depleted uranium core and a bismuth coating about the core. An optional layer of gadolinium may be disposed between the uranium core and bismuth coating. These three metals are the only materials disclosed by Kronberg. Accordingly, if one were to combine these references, what would the structure of the radiation shielding liner/core look like? Would it have Yanke et al's required ribs? Would it have Kronberg's required uranium core? Would it have Kronberg's required bismuth coating? Because of the number of problems presented by the proposed combination and opposite teachings of the references, it appears that the proposed combination is a failed attempt at impermissible hindsight using Applicant's application as the blueprint. Accordingly, it is believed that the Examiner and Applicant have agreed upon language that makes Claim 1 and all claims depending therefrom allowable.

Claims 22 and a number of claims depending therefrom stand rejected under 35 USC 103 as being unpatentable over Yanke et al in view of Kronberg and further in view of Reich (US Patent No. 5,672,883). Again, Yanke et al's non-provisional patent application is not prior art over the subject matter of the pending claims; this is because Applicant's earlier filed provisional patent application clearly conveys the subject matter of the invention of Claim 22 and all claims depending therefrom.

As was agreed upon in the interview of 2 May 2006, Claim 22 as currently presented is patentable over the references of record. In particular, the references of record fail to teach or suggest a radiopharmaceutical assembly comprising:

- a syringe having a needle, a barrel, a finger grip, and a plunger; and
- a radiopharmaceutical pig comprising:

- a base having a polymer shell that completely encloses a base shielding element of the base, the base having a first hollow center section defined therein, wherein the first hollow center section is designed to accommodate the needle and at least a portion of the barrel of the syringe; and

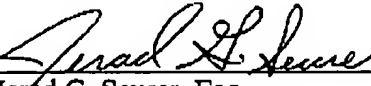
- a cap that is removably attached to the base, the cap having a polymer shell that completely encloses a cap shielding element of the cap, wherein the cap has a second hollow center section defined therein that is designed to accommodate at least a portion of the plunger of the syringe.

This proposed combination fails for all of the reasons mentioned above. In addition, Reich actually teaches away from the claimed invention. In particular, Reich teaches the use of a disposable sharps container 12 that is placed in the pig 10. Reich only teaches that the radiation shield (16, 18) is unlined/exposed on an interior of the pig. This is because a disposable sharps container 12 is designed to be simply discarded after each use in the pig. As pointed out in the interview, the radiation shielding of Reich is not completely enclosed in a shell, nor is there any motivation present to do that because the interior is protected by way of disposable sharps containers. As was agreed upon in the interview, the teaching of Reich actually teaches away from completely enclosing a radiation shielding element within a polymer shell.

Two other references (Fu et al and Hutcheson) have also been cited in rejections of various dependent claims. Since independent Claims 1 and 22 are believed to be in condition for allowance, all claims depending therefrom should also be in condition for allowance. Accordingly, the respective rejections should now be obviated.

It is believed that this application is in condition for allowance. Accordingly, early notice of allowance is hereby requested. Should the Office believe that a telephone conference would expedite allowance, the Office is invited to contact the undersigned.

Respectfully submitted,  
Mallinckrodt Inc.

  
Jerad G. Seurer, Esq.  
Reg. No. 45,467  
Tel.: (314) 654-3814